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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,638	07/15/2002	Martin Matthew Matzuk	MTN-029US	5196

959 7590 06/16/2004  
LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,638

Applicant(s)

MATZUK ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-22 are pending in the application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to an isolated nucleic polynucleotide comprising a GDF-9 regulatory element derived from a non-human GDF-9 gene selected from 10 kb DNA from 5' of the transcription site, an intron, and first 1 kb of DNA 3' of the transcription termination site, wherein said polynucleotide is greater than 261 base pair.

Group II, claim(s) 14 and 15, drawn to a method for obtaining oocyte-specific expression of a gene by transfecting an oocyte with a GDF-9 regulatory element.

Group III, claims 16 and 17, drawn to a method for obtaining testis-specific expression of a gene, the method comprising transfecting a testicular cell with a GDF-9 regulatory element.

Group IV, claim 18, drawn to a method for down regulating the expression of a gene in testis, comprising transfecting a testicular cell with a nucleotide comprising first 10 kb of DNA immediately 5' of the transcription start site of a nonhuman GDF-9 gene.

Group V, claims 19-22, drawn to a method for identifying tissue specific regulatory elements for GDF-9 expression by transfecting expression vectors comprising different regions of 5' DNA of GDF-9 gene, and comparing expression of said vectors.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-V do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group I is an isolated nucleic polynucleotide comprising a GDF-9 regulatory element

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derived from a non-human GDF-9 gene selected from 10 kb DNA from 5' of the transcription site, an intron, and first 1 kb of DNA 3' of the transcription termination site, wherein said polynucleotide is greater than 261 base pair, which is shown by Incerti et al., 1994 (IDS, see for example, Figure 2) to lack novelty or inventive step over the disclosed polynucleotide, and does not make a contribution over the prior art. Incerti et al. disclose polynucleotide from 3' of the transcription termination site of the GDF-9 gene, wherein it is larger than 261 base pair. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

The invention of the remaining groups each has a unique technical feature not shared by the other groups. The special technical feature of Group II is gene expression in oocyte, which is not shared by the remaining groups. The special technical feature of Group III is gene expression in testis, which is not shared by the remaining groups. The special technical feature of Group IV is down-regulating a gene expression in testis, which is not shared by the remaining groups. The special technical feature of Group V is a method for identifying regulatory elements for GDF-9 gene, which is not shared by the remaining group. Therefore, the unity of invention does not exist between the claims of Groups I-V.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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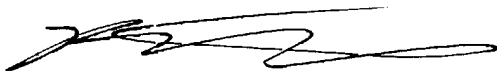
remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to be 'Celine Qian', written in a cursive style.